

- Application Serial No. 09/932,494 (Atty. Ref. No. 3320/1/US)  
Amendment dated February 23, 2005  
Reply to Office action dated August 23, 2004.

## **REMARKS**

### **Status of the claims**

Claims 1-3, 10-13, 18-25, 28-41, 46-48, 50-53, 62-83, 86-93, and 95-102 are pending. Claims 1-3, 10-13, 18-25, 28-41, 46-53, 62-83, and 86-102 stand rejected under 34 U.S.C. §103(a) as unpatentable over Mizumoto et al., U.S. Patent No. 5,576,014 ("Mizumoto") in view of Talley et al., U.S. Patent No. 5,760,068 ("Talley"). Claims 1, 22, 42, 45, 50, 94, and 95 stand rejected under §103(a) as unpatentable over Mizumoto and Talley in view of Jain et al., U.S. Patent No. 6,316,029 ("Jain").

Claims 1 and 99 have been amended as shown in the above Listing of the Claims. Support for these amendments may be found, for example, at page 24, line 28 through page 25, line 25. Claims 92 and 102 have been cancelled. No new matter has been added by these amendments.

### **Rejection of claims 1-3, 10-13, 18-25, 28-41, 46-53, 62-83, and 86-102 under §103(a)**

#### **Mizumoto in view of Talley**

Reconsideration is respectfully requested of the rejection of claims 1-3, 10-13, 18-21, 23-25, 28-41, 46-48, 51-53, 62-83, 86-93, and 96-102 under §103(a) as unpatentable over Mizumoto in view of Talley. Claims 92 and 102 have been cancelled, rendering moot their rejection.

Claim 1, as amended, requires that the step for inhibiting agglomeration of the drug is selected from the group consisting of addition of a wetting agent, means for pre-wetting the material to be granulated, and means for increasing air flow along the periphery of the granulation bowl. Similarly, independent claim 99, as amended, requires that the means for inhibiting agglomeration of the drug is selected from the group consisting of addition of a wetting agent, means for pre-wetting the material to be granulated, and means for increasing air flow along the periphery of the granulation bowl. As amended, both claims further requires that said wetting agent is selected from the group consisting of surfactants, hydrophilic polymers and clays, wherein said surfactant is selected from the group consisting of quaternary ammonium compounds, dioctyl sodium sulfosuccinate, polyoxyethylene alkylphenyl ethers, polyoxyethylene block copolymers, polyoxypropylene block copolymers, polyoxyethylene fatty acid glycerides, polyoxyethylene fatty acid oils,

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polyoxyethylene alkyl ethers, polyoxyethylene fatty acid esters, polyoxyethylene sorbitan esters, propylene glycol fatty acid esters, sodium lauryl sulfate, fatty acids, salts of fatty acids, glyceryl fatty acid esters, sorbitan esters, tyloxapol, and mixtures thereof.

Nowhere do Mizumoto or Talley, taken alone or together, describe or suggest preparing compositions according to the process of claim 1, a process that includes a step selected from the group consisting of addition of a wetting agent, means for pre-wetting the material to be granulated, and means for increasing air flow along the periphery of the granulation bowl, wherein the wetting agent is as defined in claim 1. Similarly, nowhere do Mizumoto or Talley, taken alone or together, describe or suggest a composition that requires a means for inhibiting agglomeration of the drug selected from the group consisting of addition of a wetting agent, means for pre-wetting the material to be granulated, and means for increasing air flow along the periphery of the granulation bowl, wherein the wetting agent is as defined in claim 99.

A *prima facie* showing of obviousness requires, *inter alia*, that the prior art references teach or suggest all the claim limitations. See MPEP §2143. Mizumoto and Talley, taken alone or together, do not describe or suggest all the limitations of claims 1 or 99, or of the dependent claims. Thus, the Office has not shown that claims 1-3, 10-13, 18-21, 23-25, 28-41, 46-48, 51-53, 62-83, 86-91, 93, and 96-101 are *prima facie* obvious.

Mizumoto and Talley in view of Jain

Reconsideration is respectfully requested of the rejection of claims 1, 22, 42, 45, 50, 94, and 95 as unpatentable over Mizumoto and Talley in view of Jain.

A *prima facie* showing of obviousness also requires that there is some suggestion or motivation to modify the prior art references or combine reference teachings. See MPEP §2143. Applicants respectfully assert that there is not suggestion or motivation to combine Mizumoto, Talley, and Jain, and thus that the Office has not shown that claims 1, 22, 42, 45, 50, 94, and 95 are *prima facie* obvious.

Applicants repeat their assertion that there is no teaching, suggestion or motivation to combine the cited references. The Office asserts that "Mizumoto teaches the require [sic] of tableting additives. Jain is relied upon solely for the teaching of tableting additive such as surfactant, including sodium lauryl sulfate." Mizumoto describes certain additives

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that may be used in his compositions; these include disintegrating agents, binding agents, souring agents, vesicants, artificial sweeteners, perfumes, lubricants, and coloring agents; see col. 13, lines 36-57. Mizumoto demonstrates that his compositions may successfully be prepared without the addition of, for example, surfactants such as sodium lauryl sulfate and sodium dioxide described by Jain. Similarly, as previously noted, nothing in Jain suggests the need for formulating their poorly soluble drug and surface stabilizer with the saccharide having low moldability and the saccharide having high moldability required by Mizumoto. At the very most, the formulations described by Mizumoto and Jain would be seen as alternatives to one another, which one skilled in the art would have no reason or motivation to combine. As such, Applicants respectfully request that the Examiner withdraw the rejection.

**Conclusion**

For the foregoing reasons, the Applicants submit that the present invention is now in condition for allowance. Early allowance of all pending claims is respectfully solicited.

Respectfully submitted,



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Enclosures:

Transmittal Letter  
Combined Amendment Transmittal and  
Request for Extension of Time  
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